REMARKS

The points raised by the Examiner in the Claim Objections have been overcome by amendments made above. Claim 47 has been amended to clarify the fact that the polymerizable monomer consists essentially of tropoelastin.

Claims 24, 36-55, 74, 76-98 and 100-104 are rejected under 35 U.S. C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention with regard to the terminology of "consisting essentially of". The Examiner asserts that this language is confusing and indefinite scope in that is apparently does not preclude crosslinking agents used to polymerized the tropoelastin, but it does according to Applicant's argument, preclude fibrin and polypeptides.

Section 2111.3 of the MPEP clearly states that this transitional phase limits the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristics of the claimed invention. All of the claims 24, 36-55, 74, 76-98 and 100-104 include the language which is either (a) a "biomaterial" consisting essentially of tropoelastin or (b) a "monomer" consisting essentially of tropoelastin. The subject biomaterial, typically a polymerized tropoelastin biomaterial, does not contain a crosslinking agent or a fibrin biomaterial or a polypeptide biomaterial in an amount which would materially affect the basic and novel characteristics of the claimed biomaterial. The monomer per se, typically an unpolymerized tropoelastin monomer, does not contain a crosslinking agent or a fibrin monomer or a peptide monomer in an amount which would materially affect the basic and novel characteristics of the claimed monomer. Therefore, the phase "consisting essentially of tropoelastin" does in fact preclude a crosslinking agent and/or fibrin and/or polypeptide in claims 24, 36-55, 74, 76-98 and 100-104.

Claims 1-10 12, 13, 14, 16-22, 24, 74, and 76-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-14, and

16-35 of U.S. Patent No. 6,087,552. Upon allowance of the claims pending in the subject patent application, Applicants will file a Terminal Disclaimer which disclaims the expiration date of a patent which issues based on this subject patent application beyond the expiration date of U.S. Patent No. 6,087,552.

Applicants have previously amended this application to provide that it is a continuation-in-part of U.S. Serial No. 08/341,881, filed November 15, 1994 ("USSN '881"), and a continuation-in-part of USSN 08/658,855 filed on May 31, 1996 ("USSN '855"). USSN '881 is the parent application of the Gregory States to Overcome et al reference cited by the Examiner. A Declaration of Prior Invention in the United a Cited Publication under 37 C.F.R. 1.131 ("First Declaration") has been previously presented to the Examiner. In that Declaration it is established that the invention of the pending claims was made at least by a date earlier than the effective date of the Gregory et al reference.

Applicants have provided a further Declaration to Overcome et al reference cited by the Examiner. A Declaration of Prior Invention in the United a Cited Publication under 37 C.F.R. 1.131 ("Second Declaration"), which will be delivered to the Examiner under separate cover, sets out in Exhibit A thereof further relevant descriptions of the invention which were included in a confidential Research Proposal having a date prior to the Effective Date of the Reference. As stated in that Second Declaration by one of the inventors, Dr. Kenton Gregory, the evidence as set forth in Exhibit A establishes that the invention in the subject application was conceived at least by a date earlier than the Effective Date of the Reference.

In view of Dr. Gregory's intense schedule as a cardiologist and as Director of the Oregon Medical Laser Center, the inventors believe that they were clearly diligent per se in facilitating the constructive reduction to practice of this invention by February 7, 1997. However, as further separate and distinct evidence of the inventors' diligence, Exhibits B and C are provided in the Second Declaration. These Exhibits B and C comprise copies of portions of confidential reports

issued by the OMLC covering work conducted at OMLC relating to tropoelastin conducted in the 4th Quarter of 1996 and the 1st Quarter of 1997

The parties who made the Declaration are Dr. Kenton Gregory and Mr. Andrew Barofsky, the co-inventors of the above referenced application. Dr. Gregory is also one of the co-inventors of the PCT publication which is in fact the Gregory et al reference. Dr. Gregory is an M.D. who is in the active medical practice of cardiology at Providence St. Vincent Medical Center in Portland, Oregon. He is also the Director of the Oregon Medical Laser Center which is located at the Providence St. Vincent Medical Center.

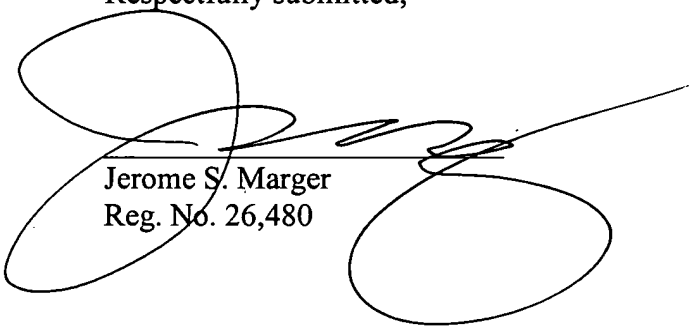
Applicants again traverse the rejection made by the Examiner that claims 47 and 48 are anticipated under 35 U.S.C. 102(b). Applicants have not made any Admissions to the effect that the claimed process of tropoelastin polymerization reads on the natural process of elastin formation in vertebrates according to Bedell-Hogan, et al in the Journal of Biological Chemistry. Applicants reiterate that In order to have anticipation under 35 USC Section 102 (b), every element of the claim must be found in the prior art reference. Claims 47 and 48 include the step of forming a biomaterial from the polymer consisting essentially of tropoelastin. This is not described in the Bedell-Hogan et al reference. Therefore, the above rejection does not constitute prima facie anticipation under 35 U.S.C. § 102 (b).

Claims 47, 48 and 53-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Labroo et al. (US 5,428,014) wherein the terminology "consisting essentially of" does not apparently preclude crosslinking agents to polymerize tropoelastin so it is the Examiner's position that it does not necessarily eliminate other polypeptides as disclosed by Labroo et al because these other polypeptides could be construed as crosslinking agents. Applicants traverse this ground of rejection in view of the remarks set forth above with respect to the rejection of claims 24, 36-55, 74, 76-98 and 100-104 under 35 U.S. C. 112, second paragraph.

Claims 101 and 102 are allowable since the rejections under 35 U.S.C. 112, 2nd paragraph as set forth in the subject Office Action have been deemed to be overcome in view of the remarks provided above in this response.

In light of the above arguments and amendments to the claims, it is requested that the Examiner reconsider his rejections and pass this case to issue. If, however, the Examiner still believes that has not responded to all of the rejections presently outstanding, he is encouraged to call the Attorney for the Applicants at the telephone number below to discuss same.

Respectfully submitted,



Jerome S. Marger
Reg. No. 26,480

Marger Johnson & McCollom, P.C.
1030 S.W. Morrison Street
Portland, Oregon 97205
(503) 222-3613

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Cancel claim 14.

19. (Amended) The method of claim [1] 18, wherein said cells which are employed to form said cellular lining are at least one of endothelial cells, epithelial cells and urothelial cells.

47. (Amended) A method for producing a biomaterial, which comprises:

providing a polymerizable monomer consisting essentially of tropoelastin;

polymerizing said polymerizable monomer to form a polymer consisting essentially of tropelastin; and

forming said biomaterial from said polymer.

100. (Amended) The method of claim 47, wherein said [tropoelastin] biomaterial is attached to a tissue substate.

103. (Amended) A method for producing a tropoelastin biomaterial, which comprises:

providing a monomer consisting essentially of tropoelastin;

polymerizing said tropoelastic monomer to form a polymer consisting essentially of tropoelastin;

forming a tropoelastin biomaterial from said tropoelastin polymer; and

forming a cellular lining of human cells on one of the major surfaces of said tropoelastin biomaterial.